Cynthia S. Betz
Mark M. Makhail
MCCARTER & ENGLISH, LLP
4 Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 622-4444
cbetz@mccarter.com
mmakhail@mccarter.com

Megan K. Bannigan
DEBEVOISE & PLIMPTON LLP
66 Hudson Boulevard
New York, New York 10001
(212) 909-6000
mkbannigan@debevoise.com

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. NOVADOZ PHARMACEUTICALS LLC, MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, Defendants.	Civil Action No. 25-849

PLAINTIFFS' MEMORANDUM OF LAW IN RESPONSE TO THE COURT'S ORDER FOR BRIEFING ON RECONSIDERATION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Other Authorities

The Novartis[1] Plaintiffs respectfully submit this brief in response to the Court's April 4, 2025 Order at ECF No. 43 ("Reconsideration Order") and in opposition to the MSN Defendants' Memorandum of Law in Response to the Court's Order at ECF No. 45 ("Recons. Br.").

PRELIMINARY STATEMENT

No intervening change in law, new evidence, or need to correct a legal or factual error warrants disturbing this Court's PI. MSN's arguments primarily misconstrue the law, relitigate previously rejected positions, or raise new arguments foreclosed at this procedural posture. To the extent there are any errors, those errors helped, rather than hurt MSN. Accordingly, this Court should decline to reconsider its Order and Opinion, or in the alternative issue a new opinion elaborating on its reasoning and findings supporting the grant of a PI.

LEGAL STANDARD

"[R]econsideration is an extraordinary remedy, that is granted very sparingly[.]" *Clark v. Prudential Ins. Co. of Am.*, 940 F. Supp. 2d 186, 189 (D.N.J. 2013) (internal quotation omitted). The grounds for reconsideration include: (1) an intervening change in controlling law, (2) the availability of new evidence that was not previously available, and (3) the need to correct a clear error of law or fact or to

[1] Defined terms mirror those in the Pls.' Mem. of Law in Opp'n to Defs.' Motion for a Stay, ECF No. 42 ("Novartis's Opposition" or "Opp'n to Stay").

prevent manifest injustice. *Howard Hess Dental Lab'ys Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 251 (3d Cir. 2010). The law of the case doctrine limits the Court's *sua sponte* reconsideration to similar grounds. *In re Pharmacy Benefit Managers Antitrust Litig.*, 582 F.3d 432, 439 (3d Cir. 2009) (identifying "extraordinary circumstances" that allow a court to revisit prior decisions).

ARGUMENT

I. The Court Has Jurisdiction to Reconsider Its Order and Opinion.

As an initial matter, MSN is mistaken that its notice of appeal has divested this Court of jurisdiction to reconsider its Order and Opinion. "[W]hen a party files a timely motion to reconsider, the district court retains jurisdiction to decide that motion." *U.S. v. Banks*, 674 F. App'x 121, 124 (3d Cir. 2017) (citing Fed. R. App. P. 4); *Ortho Pharm. Corp. v. Amgen, Inc.*, 887 F.2d 460, 463 (3d Cir. 1989) (same for PI). MSN has asked the Court to treat its filings as reconsideration motions (Recons. Br. at 8 n.5), which were timely filed under Fed. R. Civ. P. 59(e). *See Wiest v. Lynch*, 710 F.3d 121, 127 (3d Cir. 2013*); see also Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 2011 WL 4916397, at *3, n.3 (M.D. Pa. Oct. 17, 2011). Even if MSN were correct, this Court retains jurisdiction to clarify and/or further explain the basis for the PI to "assist the Court of Appeals in its determination." *In re Stone Res., Inc.*, 482 F. App'x 719, 721 n.1 (3d Cir. 2012).

II. The Court Applied the Correct Legal Standard in Evaluating the Validity of the ENTRESTO® Trade Dresses.

A. The ENTRESTO® Trade Dresses Are Not Functional.

MSN offers no reason for the Court to revisit its finding that the ENTRESTO® Trade Dresses are non-functional under the law. (*See* Op. at 5–10). MSN contends that the Court erred by (1) solely considering the existence of alternative designs, and (2) failing to address evidence of the functionality of pill sizes and shapes. (*See* Recons. Br. at 4–5; *see also* Defs.' Reply Mem. of Law in Supp. of Mot. for a Stay, ECF No. 44 ("Reply to Stay"), at 8–11). Neither of these arguments has merit or supports reconsideration based on error.

First, the Court did not rely ***solely*** on the presence of alternative designs in determining that the ENTRESTO® Trade Dresses are nonfunctional. (*See* Op. at 5–10 (distinguishing *Shire US Inc. v. Bar Laboratories, Inc.*;[2] rejecting arguments that the ENTRESTO® colors are functional and therapeutic adherence requires copying; and noting evidence there was no reason for smaller low dose tablets)). While the Court considered the presence of alternative designs (and noted that MSN could have picked a different color, size, or shape for its tablets (Op. at 9)), that consideration itself cannot constitute legal error. *See Ezaki Glico Kabushiki Kaisha v. Lotte Int'l*

[2] Re-litigation of arguments under *Shire* is not proper on reconsideration. (*See* Op. at 9 (properly distinguishing *Shire* on its facts); Motion at 18–19; Opp'n to Stay at 27–28; Reply to Stay at 3–4). No error or intervening change of law or fact warrants disturbing the Court's Opinion distinguishing *Shire*. *See McAdams v. United States*, 2024 WL 4100368, at *2–3 (D.N.J. Sept. 6, 2024) ("A motion for reconsideration is improper when it is used solely to ask the court to rethink what it has already thought through—rightly or wrongly.").

Am. Corp., 986 F.3d 250, 258 (3d Cir. 2021) (acknowledging that "the existence of other workable designs is relevant evidence").

Second, contrary to MSN's arguments, a dissection of the ENTRESTO® Trade Dresses is not required. Instead, "a ***combination*** of functional and non-functional features can be protected as trade dress, so long as the non-functional features help make the overall design distinctive and identify its source." *Id.*; *Am. Greetings Corp. v. Dan-Dee Imports, Inc.*, 807 F.2d 1136, 1143 (3d Cir. 1986) ("Indeed, virtually every product is a combination of functional and non-functional features and a rule denying protection to any combination of features including a functional one would emasculate the law of trade dress infringement."). Here, the ENTRESTO® Trade Dresses include non-functional elements,[3] such that the overall ***combinations*** of features are non-functional,[4] and as this Court previously acknowledged, serve to distinguish ENTRESTO® in the market for heart failure drugs. (Op. at 6; *see also* Opp'n to Stay at 28–29); *compare Ezaki*, 986 F.3d at 259

[3] Novartis's Opposition sets forth why color is non-functional. (*See* Opp'n to Stay at 26). In addition, size is similarly non-functional, as there was no reason to vary the sizing of the ENTRESTO® tablets. (*See* Op. at 6).

[4] MSN's argument that a generic must look like the branded equivalent to ensure therapeutic adherence is essentially an argument that MSN needed to copy ENTRESTO® to ***facilitate confusion***. This argument has been rejected both by other courts, *see, e.g.*, *Ciba-Geigy Corp. v. Bolar Pharm. Co.*, 547 F. Supp. 1095, 1104 (D.N.J. 1982), *aff'd* 719 F.2d 56 (3d Cir. 1983), and this one (*see* Op. at 8–9). It is not proper ground for reconsideration. *See McAdams*, 2024 WL 4100368, at *3; (*see also* Opp'n to Stay at 29–31) (explaining Mr. Martin Shimer's opinions and FDA guidance do not support a finding to the contrary)).

(finding "***[e]very feature*** . . .relates to the practical functions of holding, eating, sharing, or packing the snack").

B. The Court Properly Determined That the ENTRESTO® Trade Dresses Have Acquired Secondary Meaning.

MSN provides no new reason (much less extraordinary circumstances) for this Court to reconsider its holding that the ENTRESTO® Trade Dresses have "likely achieved secondary meaning." (Op. at 12). The Court did not err in rejecting MSN's prior arguments. (*See* Opp'n to Stay at 32–34; Br. at 19–23).[5]

III. The Court Did Not Err in Finding a Likelihood of Irreparable Harm.

The parties agree Novartis was entitled to a presumption of irreparable harm, (*see* Opp'n to Stay at 11–12; Motion at 8), but disagree on the import of that presumption, (*see* Opp'n to Stay at 11–12; Motion at 8–17). The Court's finding on irreparable harm was correct, and a presumption only amplifies that. Neither MSN's argument that Novartis allegedly delayed in seeking a PI, nor its argument that ENTRESTO® consumers are sophisticated dictates a different result.

A. Delay Did Not Preclude a Finding of Irreparable Harm.

All but one of MSN's delay arguments are merely repeat arguments considered and rejected by this Court. (*See* Op. at 15–17). Although MSN fixates

[5] Even if the Court credits MSN's attacks on Dr. Arash Nayeri's testimony on his recognition of the ENTRESTO® Trade Dresses, (*see* Reply to Stay at 13), the Court is not required to rely on direct consumer testimony to find secondary meaning, (*see* Op. at 12 (noting consumer testimony is "not dispositive")).

on the length of Novartis's purported delay, it has never once identified why that delay undercuts Novartis's argument that its injury was actual and irreparable. *Sunquest Info. Sys., Inc. v. Park City Sols., Inc.*, 130 F. Supp. 2d 680, 698 (W.D. Pa. 2000) ("[A] delay in filing suit will not rebut the presumption of irreparable harm" absent evidence the plaintiff knew "how severe the infringement is."). The cases MSN cites emphasize the fact-specific nature of a delay analysis. (*See* Opp'n to Stay at 18, 20–22). Here, Novartis acted upon learning MSN's launch was imminent after a diligent investigation and the public disclosure of information subject to the constraints of the relevant protective orders. (S*ee id*. at 18–22).

MSN's new argument—that Novartis should have evaded or sought relief from a protective order that prevented it from acting earlier—is meritless. (*See id.* at 19–20). *Cambridge Literary Properties, Ltd. v. W. Goebel Porzellanfabrik G.m.b.H. & Co. Kg.*, 448 F. Supp. 2d 244 (D. Mass. 2006), *aff'd*, 510 F.3d 77 (1st Cir. 2007) is an out-of-Circuit decision that is nearly twenty years old. It is hardly an intervening change in the controlling law warranting reconsideration. Even if accepted, the idea that Novartis should or could have acted here on protected information is completely unfounded. (*See* Opp'n to Stay at 19 n. 6).[6]

B. Consumer Sophistication Does Not Preclude a Finding of

[6] MSN incorrectly suggests the protective order broadly gave "Novartis's in-house counsel" access to protected information. (Reply to Stay at 5 n.4). The protective order gave access to only certain designated individuals (who are not responsible for Novartis's trademark strategy). (Silver Decl. ¶¶ 12–14, 30–31).

Irreparable Harm.

MSN's new argument that it can overcome any presumption of irreparable harm because the relevant consumers are sophisticated, fails both procedurally and substantively. Procedurally, MSN is precluded from relying on this new argument in connection with a motion for reconsideration. *Boyko v. Am. Int'l Grp., Inc.*, 2012 WL 2132390, at *2 (D.N.J. June 12, 2012) (motion "may address only those matters of fact or issues of law that the parties presented to, but were not considered by, the court"). MSN could have raised this argument in its Opposition Brief but failed to do so. (*See* Opp'n at 32; *see also* Opp'n to Stay at 22–23).

Substantively, MSN's reliance on the sophistication of consumers fails for two reasons. *First*, MSN's argument is premised upon an error of fact and law. The exclusion of patients from the relevant population and determination that "the relevant market consists primarily of medical professionals," (Op. at 14), disregards both clear law and evidence (*see* Br. at 26–27). But that exclusion helped, rather than hurt, MSN. As indicated by the significant evidence of consumer-facing marketing produced by Novartis, patients are very aware of their pharmaceutical options and part of the consumer class here. (*See id*. at 9); *Sanofi-Aventis v. Advancis Pharm. Corp.*, 453 F. Supp. 2d 834, 851 (D. Del. 2006) (treating patients as relevant consumers of a prescription drug "[i]n an age where direct-to-consumer advertising is becoming more popular"). While HCPs may prescribe a certain medication, a

patient can advocate for or refuse to take a certain brand of drug, even if prescribed, as they ultimately pay for and consume the product. As a result, patients should be treated as relevant consumers and consumer sophistication must be assessed based on the less-sophisticated patient population. (Br. at 26 (citing *Sabinsa Corp. v. Creative Compounds, LLC*, 609 F.3d 175, 186 (3d Cir. 2010)); *see* Op. at 14).[7]

Second, even assuming HCPs are the only relevant consumers, it is not enough for MSN to simply assert consumers are sophisticated. To rebut the presumption of irreparable harm, MSN must provide at least some evidence of why that sophistication matters. *Nichino Am., Inc. v. Valent U.S.A. LLC*, 44 F.4th 180, 186 (3d Cir. 2022) (defendant required "to introduce evidence sufficient for a reasonable factfinder to conclude that the consumer confusion is unlikely to cause irreparable harm"). While "light," this is still a "burden of production." *Id.* at 187. Here, MSN has provided no such evidence. *See id.* (considering evidence from defendant that "ma[de] it plausible to conclude that consumers will confirm their pesticide selection before staking their farms on an inadvertent purchase"). There is no evidence that sophisticated consumers would not be confused by MSN's tablets that have the same size, shape, and color as ENTRESTO®. Without that evidence, MSN has not

[7] If desired, the Court may revisit this finding because Novartis cited this precedent and the Court did not acknowledge it. *See Howmedica Osteonics Corp. v. Zimmer, Inc.*, 2009 WL 2923077, at *2 (D.N.J. Sept. 9, 2009) (motion proper "only when 'dispositive factual matters or controlling decisions of law' were brought to the court's attention but not considered").

rebutted the presumption of irreparable harm.

C. Novartis Has Produced Sufficient Evidence to Show It Was Likely to Suffer Irreparable Harm.

Regardless, Novartis produced evidence that (1) it has cultivated strong goodwill in its ENTRESTO® Trade Dresses, (2) MSN's use of the ENTRESTO® Trade Dresses is likely to cause consumer confusion, (3) Novartis has no control over the quality of the MSN Drug, and (4) Novartis has concerns about the dosing instructions provided with the MSN Drug. (*See* Op. at 17–18; Opp'n to Stay at 13–14).[8] Prior to launch, and without access to further evidence from MSN, this is a sufficient showing from Novartis to establish it is likely to be irreparably harmed.[9]

IV. The Court Properly Balanced the PI Factors and Its Opinion Would Only Be Strengthened by Supplemental Analysis.

The Court balanced all four PI factors in granting Novartis's motion for a PI. (*See* Opp'n to Stay at 3–4). While the Court focused its analysis on the two "most critical" factors, it also weighed the parties' harms and public interest before finding that the factors, as a whole, favored a PI. (Op. at 5–18; *see also* Opp'n to Stay at

[8] MSN's continued attempts to relitigate *Novartis Pharmaceuticals Corp. v. Becerra*, 2024 WL 3823270 (D.D.C. Aug. 13, 2024)—an out-of-Circuit case involving different issues—are inappropriate and fall short of MSN's burden of production needed to rebut a presumption of irreparable harm.

[9] *See New York City Triathlon, LLC v. NYC Triathlon Club, Inc.*, 704 F. Supp. 2d 305, 343 (S.D.N.Y. 2010) (finding irreparable harm in the absence of a presumption where plaintiff demonstrated "prospective loss of [its] goodwill" through evidence it had "amassed substantial goodwill" over 10 years of operations, and evidence that consumers were likely to be confused).

34–35). Plus, even if "the Court did not discuss in detail each factor for" a PI, that "does not mean that the Court did not consider them." *Wells v. Nelson*, 2017 WL 2831169, at *2 (D.N.J. June 30, 2017) (denying motion for reconsideration of PI). This Court's reasoning is distinct from cases within this Circuit finding an insufficient balancing of the PI factors based on silence or a cursory sentence. (*See* Opp'n to Stay at 35).

MSN has provided no new harms that dictate a different result upon reconsideration. At the PI stage, MSN detailed the harms that it will purportedly face if enjoined, and the Court acknowledged them. (Op. at 18; *see also* Opp'n to Stay at 8–9, 35). The Court's finding is supported by controlling law in this Circuit (Br. at 38–40), and MSN has provided no newly discovered evidence of harms or intervening changes in the law that warrant reconsideration.

Finally, the Court's public harm analysis was proper. MSN cannot point to any changes in the law or legal error in the Court's decision here to protect the public from confusion. (*See id*. at 34–37; Opp'n to Stay at 37–38).

CONCLUSION

For the reasons set forth above (and in its Opposition to MSN's Motion to Stay), Novartis requests that the Court decline to reconsider its Order and Opinion or, in the alternative, correct any prior perceived errors and issue an Opinion still finding in favor of Novartis and continuing the current PI.

Respectfully submitted,

Dated: April 9, 2025

By: /s/ *Mark M. Makhail*

Cynthia S. Betz
Mark M. Makhail
MCCARTER & ENGLISH, LLP
4 Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 622-4444
cbetz@mccarter.com
mmakhail@mccarter.com

Megan K. Bannigan
Kathryn C. Saba (**pro hac vice*)
Anna M. Rennich (**pro hac vice*)
DEBEVOISE & PLIMPTON LLP
66 Hudson Boulevard
New York, New York 10001
Telephone: 212.909.6000
mkbannigan@debevoise.com
ksaba@debevoise.com
amrennich@debevoise.com

Counsel for Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation